

IDS 12/14/01

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 3100-0001.20	SERIAL NO.: CIP of filed 10/25/01 (Serial No. not yet assigned)
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		APPLICANT: Bret BERNER et al.	
		FILING DATE: Concurrently herewith	GROUP: Unassigned

U.S. PATENT DOCUMENTS

EXAMINER INITIALS	CITE NO.	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
J	AA	4,695,467	9/22/87	Uemura et al.			
	AB	4,910,021	3/20/90	Davis et al.			
	AC	5,002,772	3/26/91	Curatolo et al.			
	AD	5,007,790	4/16/91	Shell			
	AE	5,425,950	6/20/95	Dandiker et al.			
	AF	5,582,837	10/10/96	Shell			
	AG	5,738,874	4/14/98	Conte et al.			
	AH	5,783,212	7/21/98	Fassihi et al.			
	AI	5,840,332	11/24/98	Lerner et al.			
	AJ	5,891,474	4/6/99	Busetti et al.			
	AK	5,945,125	8/31/99	Kim			
	AL	5,972,389	10/26/99	Shell et al.			
	AM	6,027,748	2/22/00	Conte et al.			
	AN	6,093,420	7/25/00	Baichwal			
	AO	6,120,803	9/19/00	Wong et al.			
	AP	6,221,395	4/24/01	Maggi et al.			9/1/98

OTHER DOCUMENT — NONPATENT LITERATURE DOCUMENT

EXAMINER INITIALS	CITE NO.	INCLUDE NAME OF AUTHOR, TITLE OF ARTICLE (IF APPROPRIATE), TITLE OF PUBLICATION, DATE, PAGE(S), VOLUME-ISSUE NUMBER(S), PUBLISHER, AND PLACE OF PUBLICATION
J	AQ	Katori et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on <i>in Vitro/in Vivo</i> Correlation," <i>Pharmaceutical Research</i> 12(2):237-243.

EXAMINER SIGNATURE:

DATE CONSIDERED:

9/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

105 12/18/01

Atty Dkt No. 3100-0001.20

U.S. PATENT DOCUMENTS		
PATENT NO.	ISSUE DATE	PATENTEE
4,695,467	9/22/87	Uemura et al.
4,910,021	3/20/90	Davis et al.
5,002,772	3/26/91	Curatolo et al.
5,007,790	4/16/91	Shell
5,425,950	6/20/95	Dandiker et al.
5,582,837	10/10/96	Shell
5,738,874	4/14/98	Conte et al.
5,783,212	7/21/98	Fassihi et al.
5,840,332	11/24/98	Lerner et al.
5,891,474	4/6/99	Busetti et al.
5,945,125	8/31/99	Kim
5,972,389	10/26/99	Shell et al.
6,027,748	2/22/00	Conte et al.
6,093,420	7/25/00	Baichwal
6,120,803	9/19/00	Wong et al.
6,221,395	4/24/01	Maggi et al.

PTO
12/18/01
10/24/01
12/18/01

OTHER DOCUMENT
Katori et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on <i>in Vitro/in Vivo</i> Correlation," <i>Pharmaceutical Research</i> 12(2):237-243.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

125 4/7/03

Atty Dkt No. 3100-0001.20
PATENT



I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, Washington, DC 20231" on

April 4, 2003
4-03
Margo O'Malley
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Bret BERNER et al.

Confirmation No.: 5481

Serial No.: 10/024,932

Group Art Unit: 1615

Filing Date: December 18, 2001

Examiner: Unassigned

Title: GASTRIC RETENTIVE ORAL DOSAGE FORM WITH RESTRICTED DRUG RELEASE IN THE LOWER GASTROINTESTINAL TRACT

RECEIVED
APR 09 2003
TECH CENTER 1600/2800

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, DC 20231

Sir:

This is a Second Supplemental Information Disclosure Statement submitted for the Examiner's consideration. Applicants respectfully request that the Examiner review and make of record the references identified below.

PTO-1449 forms listing the references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the forms to indicate that the references have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
4,434,153	2/28/84	Urquhart et al.
4,690,824	9/1/87	Powell et al.
4,748,023	5/31/88	Tamás et al.
4,786,503	11/22/88	Edgren et al.
4,839,177	6/13/89	Colombo et al.
4,851,232	7/25/89	Urquhart et al.
4,865,849	9/12/89	Conte et al.
5,064,656	11/12/91	Gergely et al.
5,085,865	2/4/92	Nayak
5,213,808	5/25/93	Bar-Shalom et al.
5,232,704	8/3/93	Franz et al.
5,393,765	2/28/95	Infeld et al.
5,422,123	6/6/95	Conte et al.

IDS 4/2/03

Atty Dkt No. 3100-0001.20

Serial No. 10/024,932

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
5,458,887	10/17/95	Chen et al.
5,458,888	10/17/95	Chen
5,464,633	11/7/95	Conte et al.
5,472,708	12/5/95	Chen
5,487,901	1/30/96	Conte et al.
5,508,040	4/16/96	Chen
5,549,913	8/27/96	Colombo et al.
5,609,590	3/11/97	Herbig et al.
5,626,874	5/6/97	Conte et al.
5,650,169	7/22/97	Conte et al.
5,651,985	7/29/97	Penners et al.
5,681,583	10/28/97	Conte et al.
5,688,776	11/18/97	Bauer et al.
5,736,159	4/7/98	Chen et al.
5,780,057	7/14/98	Conte et al.
5,811,126	9/22/98	Krishnamurthy
5,837,379	11/17/98	Chen et al.
5,840,329	11/24/98	Bai
5,861,173	1/19/99	Nishioka et al.
5,897,874	4/27/99	Stevens et al.
5,916,595	6/29/99	Chen et al.
6,033,685	3/7/00	Qiu et al.
6,207,197	3/27/01	Illum et al.
6,261,601	7/17/01	Talwar et al.
6,340,475	01/22/02	Shell et al.
6,368,628	4/9/02	Seth
6,451,808	9/17/02	Cowles
6,488,962	12/3/02	Berner et al.
2001/0018070	8/30/01	Shell et al.
Serial No. 09/425,491	Filed 10/22/99	Shell et al.
Serial No. 10/029,134	Filed 10/25/01	Gusler et al.
Serial No. 10/045,823	Filed 11/6/01	Shell et al.
Serial No. 10/066,146	Filed 2/1/02	Lim et al.
Serial No. 10/152,914	Filed 5/20/02	Fara et al.

FOREIGN PATENT DOCUMENTS		
Document No.	Publication Date	Country
EP 0598309 B1	1/28/98	Europe
EP 0795324 A2	9/17/97	Europe
WO 96/32097 A1	10/17/96	PCT
WO 98/55107 A1	12/10/98	PCT
WO 00/23045 A1	4/27/00	PCT
WO 00/38650 A1	7/6/00	PCT

IDS 4/7/03

Atty Dkt No. 3100-0001.20

Serial No. 10/024,932

FOREIGN PATENT DOCUMENTS		
Document No.	Publication Date	Country
WO 01/32217 A3	5/10/01	PCT
WO 01/56544 A3	8/9/01	PCT
WO 01/97783 A1	12/27/01	PCT
WO 02/083687 A1	10/24/02	PCT

NONPATENT DOCUMENTS	
Abrahamsson, et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.	
Apicella et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.	
Columbo et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> 63:43-48.	
Davis et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.	
Deshpande et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention," <i>Pharmaceutical Research</i> 14(6):815-819.	
Gusler et al. (June 2001), "Pharmacokinetics of Metformin Gastric-Retentive Tablets in Healthy Volunteers," <i>The Journal of Clinical Pharmacology</i> 41(6):655-661.	
Huber et al. (1966), "Utilization of Hydrophilic Gums for the Control of Drug Release from Tablet Formulations. I. Disintegration and Dissolution Behavior," <i>Journal of Pharmaceutical Sciences</i> 55(9):974-976.	
Hwang et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 15(3):243-284.	
Kim (1995), "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," <i>Journal of Pharmaceutical Sciences</i> 84(3):303-306.	
Korsmeyer et al. (1983), "Mechanisms of Solute Release from Porous Hydrophilic Polymers," <i>International Journal of Pharmaceutics</i> 15:25-35.	
Maggi et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in Controlled Release Dosage Forms," <i>International Journal of Pharmaceutics</i> 195:229-238.	
Rao et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> 48:1-13.	
Reynolds et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> 87(9):1115-1123.	
Siepmann et al. (1999) "A New Model Describing the Swelling and Drug Release Kinetics from Hydroxypropyl Methylcellulose Tablets," <i>Journal of Pharmaceutical Sciences</i> 88(1):65-72.	
Yang et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.	

This Second Supplemental Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the



105 1/29/04

Atty Dkt No. 3100-0001.20
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Bret BERNER et al.

Confirmation No.: 5481

Serial No.: 10/024,932

Group Art Unit: 1615

Filing Date: December 18, 2001

Examiner: Edward J. WEBMAN

Title: GASTRIC RETENTIVE ORAL DOSAGE FORM WITH RESTRICTED DRUG RELEASE IN
THE LOWER GASTROINTESTINAL TRACT

RESUBMITTED INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia

Sir:

Further to the Examiner's request in the Office Action of September 29, 2003, the Information Disclosure Statement of December 18, 2001, is resubmitted per the Examiner's request. In the Office Action, the Examiner indicated that the cited references were not available to the Examiner. As the cited references are provided with this paper, applicants respectfully request that the Examiner review and make of record the references identified below.

A PTO-1449 form listing the cited references is also resubmitted for the Examiner's convenience and is attached to this paper. Upon review of the references submitted herewith, applicants respectfully request that the Examiner initial and return a copy of the PTO-1449 to the applicants in order so that applicants will have a written record that the references submitted herewith have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
4,695,467	9/22/87	Uemura et al.
4,910,021	3/20/90	Davis et al.
5,002,772	3/26/91	Curatolo et al.
5,007,790	4/16/91	Shell
5,425,950	6/20/95	Dandiker et al.
5,582,837	10/10/96	Shell
5,738,874	4/14/98	Conte et al.
5,783,212	7/21/98	Fassihi et al.
5,840,332	11/24/98	Lerner et al.

U.S. PATENT DOCUMENTS			RECEIVED FEB 05 2004 TECH CENTER 1600/2900
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant	
5,891,474	4/6/99	Busetti et al.	
5,945,125	8/31/99	Kim	
5,972,389	10/26/99	Shelton et al.	
6,027,748	2/22/00	Conte et al.	
6,093,420	7/25/00	Baichwal	
6,120,803	9/19/00	Wong et al.	
6,221,395	4/24/01	Maggi et al.	

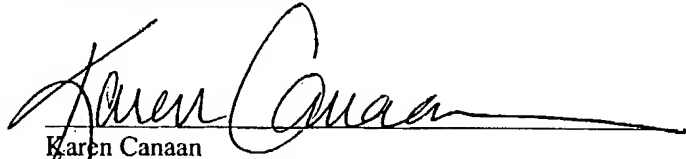
NONPATENT DOCUMENTS	
Katori et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on <i>in Vitro/in Vivo</i> Correlation," <i>Pharmaceutical Research</i> 12(2):237-243.	

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

The attached return post-card indicates that the cited references were mailed along with the Information Disclosure Statement and PTO-1449 on December 18, 2001; accordingly, applicants submit that this resubmission of the Information Disclosure Statement of December 18, 2001, should not be subject to a fee. Nevertheless, if the Office deems that a fee is necessary, then the Office is authorized to charge the appropriate fee to Deposit Account No. 18-0580.

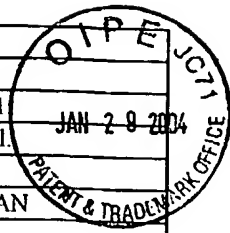
Respectfully submitted,

By:


Karen Canaan
Registration No. 42,382

REED & EBERLE LLP
800 Menlo Avenue, Suite 210
Menlo Park, California 94025
(650) 330-0900 Telephone
(650) 330-0980 Facsimile

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			<i>Complete if Known</i>		
			Application Number	10/024,932	
			Filing Date	December 18, 2001	
			First Named Inventor	Bret BERNER et al.	
			Art Unit	1615	
			Examiner Name	Edward J. WEBMAN	
Sheet	1	of	3	Attorney Docket Number	3100-0001.20



U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
J	AA	4,695,467	9/22/87	Uemura et al.			
J	AB	4,910,021	3/20/90	Davis et al.			
J	AC	5,002,772	3/26/91	Curatolo et al.			
J	AD	5,007,790	4/16/91	Shell			
J	AE	5,425,950	6/20/95	Dandiker et al.			
J	AF	5,582,837	10/10/96	Shell			
J	AG	5,738,874	4/14/98	Conte et al.			
J	AH	5,783,212	7/21/98	Fassihi et al.			
J	AI	5,840,332	11/24/98	Lerner et al.			
J	AJ	5,891,474	4/6/99	Busetti et al.			
J	AK	5,945,125	8/31/99	Kim			
J	AL	5,972,389	10/26/99	Shell et al.			
J	AM	6,027,748	2/22/00	Conte et al.			
J	AN	6,093,420	7/25/00	Baichwal			
J	AO	6,120,803	9/19/00	Wong et al.			
J	AP	6,221,395	4/24/01	Maggi et al.			9/1/98



OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
J	AQ	Katori et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on <i>in Vitro/in Vivo</i> Correlation," <i>Pharmaceutical Research</i> 12(2):237-243.	

Examiner Signature		Date Considered	9/09
--------------------	--	-----------------	------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Bret BERNER et al.

Confirmation No.: 5481

Serial No.: 10/024,932

Group Art Unit: 1615

Filing Date: December 18, 2001

Examiner: Edward J. WEBMAN

Title: GASTRIC RETENTIVE ORAL DOSAGE FORM WITH RESTRICTED DRUG RELEASE IN
THE LOWER GASTROINTESTINAL TRACT

RESUBMITTED INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia

Sir:

Further to the Examiner's request in the Office Action of September 29, 2003, the Information Disclosure Statement of April 4, 2003, is resubmitted per the Examiner's request. In the Office Action, the Examiner indicated that the cited references were not available to the Examiner. As the cited references are provided with this paper, applicants respectfully request that the Examiner review and make of record the references identified below.

A PTO-1449 form listing the cited references is also resubmitted for the Examiner's convenience and is attached to this paper. Upon review of the references submitted herewith, applicants respectfully request that the Examiner initial and return a copy of the PTO-1449 to the applicants in order so that applicants will have a written record that the references submitted herewith have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
4,434,153	2/28/84	Urquhart et al.
4,690,824	9/1/87	Powell et al.
4,748,023	5/31/88	Tamás et al.
4,786,503	11/22/88	Edgren et al.
4,839,177	6/13/89	Colombo et al.
4,851,232	7/25/89	Urquhart et al.
4,865,849	9/12/89	Conte et al.
5,064,656	11/12/91	Gergely et al.
5,085,865	2/4/92	Nayak
5,213,808	5/25/93	Bar-Shalom et al.
5,232,704	8/3/93	Franz et al.

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
5,393,765	2/28/95	Infeld et al.
5,422,123	6/6/95	Conte et al.
5,458,887	10/17/95	Chen et al.
5,458,888	10/17/95	Chen
5,464,633	11/7/95	Conte et al.
5,472,708	12/5/95	Chen
5,487,901	1/30/96	Conte et al.
5,508,040	4/16/96	Chen
5,549,913	8/27/96	Colombo et al.
5,609,590	3/11/97	Herbig et al.
5,626,874	5/6/97	Conte et al.
5,650,169	7/22/97	Conte et al.
5,651,985	7/29/97	Penners et al.
5,681,583	10/28/97	Conte et al.
5,688,776	11/18/97	Bauer et al.
5,736,159	4/7/98	Chen et al.
5,780,057	7/14/98	Conte et al.
5,811,126	9/22/98	Krishnamurthy
5,837,379	11/17/98	Chen et al.
5,840,329	11/24/98	Bai
5,861,173	1/19/99	Nishioka et al.
5,897,874	4/27/99	Stevens et al.
5,916,595	6/29/99	Chen et al.
6,033,685	3/7/00	Qiu et al.
6,207,197	3/27/01	Illum et al.
6,261,601	7/17/01	Talwar et al.
6,340,475	01/22/02	Shell et al.
6,368,628	4/9/02	Seth
6,451,808	9/17/02	Cowles
6,488,962	12/3/02	Berner et al.
2001/0018070	8/30/01	Shell et al.
Serial No. 09/425,491	Filed 10/22/99	Shell et al.
Serial No. 10/029,134	Filed 10/25/01	Gusler et al.
Serial No. 10/045,823	Filed 11/6/01	Shell et al.
Serial No. 10/066,146	Filed 2/1/02	Lim et al.
Serial No. 10/152,914	Filed 5/20/02	Fara et al.

FOREIGN PATENT DOCUMENTS		
Document No.	Publication Date	Country
EP 0598309 B1	1/28/98	Europe
EP 0795324 A2	9/17/97	Europe
WO 96/32097 A1	10/17/96	PCT
WO 98/55107 A1	12/10/98	PCT
WO 00/23045 A1	4/27/00	PCT
WO 00/38650 A1	7/6/00	PCT
WO 01/32217 A3	5/10/01	PCT
WO 01/56544 A3	8/9/01	PCT

FOREIGN PATENT DOCUMENTS		
Document No.	Publication Date	Country
WO 01/97783 A1	12/27/01	PCT
WO 02/083687 A1	10/24/02	PCT

NONPATENT DOCUMENTS
Abrahamsson, et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.
Apicella et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.
Columbo et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> 63:43-48.
Davis et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.
Deshpande et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention," <i>Pharmaceutical Research</i> 14(6):815-819.
Gusler et al. (June 2001), "Pharmacokinetics of Metformin Gastric-Retentive Tablets in Healthy Volunteers," <i>The Journal of Clinical Pharmacology</i> 41(6):655-661.
Huber et al. (1966), "Utilization of Hydrophilic Gums for the Control of Drug Release from Tablet Formulations. I. Disintegration and Dissolution Behavior," <i>Journal of Pharmaceutical Sciences</i> 55(9):974-976.
Hwang et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 15(3):243-284.
Kim (1995), "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," <i>Journal of Pharmaceutical Sciences</i> 84(3):303-306.
Korsmeyer et al. (1983), "Mechanisms of Solute Release from Porous Hydrophilic Polymers," <i>International Journal of Pharmaceutics</i> 15:25-35.
Maggi et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in Controlled Release Dosage Forms," <i>International Journal of Pharmaceutics</i> 195:229-238.
Rao et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> 48:1-13.
Reynolds et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> 87(9):1115-1123.
Siepmann et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> 16(11):1748-1756.
Yang et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Sheet	1	of	3	Application Number	10/024,932
				Filing Date	December 18, 2001
				First Named Inventor	Bret BERNER et al.
				Art Unit	1615
				Examiner Name	Edward J. WEBMAN
				Attorney Docket Number	3100-0001.20

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
J	AW	4,434,153	2/28/84	Urquhart et al.			
J	AX	4,690,824	9/1/87	Powell et al.		1	
	AY	4,748,023	5/31/88	Tamás et al.			
	AZ	4,786,503	11/22/88	Edgren et al.			
	BA	4,839,177	6/13/89	Colombo et al.			
	BB	4,851,232	7/25/89	Urquhart et al.			
	BC	4,865,849	9/12/89	Conte et al.			
	BD	5,064,656	11/12/91	Gergely et al.			
	BE	5,085,865	2/4/92	Nayak			
	BF	5,213,808	5/25/93	Bar-Shalom et al.			
	BG	5,232,704	8/3/93	Franz et al.			
	BH	5,393,765	2/28/95	Infeld et al.			
	BI	5,422,123	6/6/95	Conte et al.			
	BJ	5,458,887	10/17/95	Chen et al.			
	BK	5,458,888	10/17/95	Chen			
	BL	5,464,633	11/7/95	Conte et al.			
	BM	5,472,708	12/5/95	Chen			
	BN	5,487,901	1/30/96	Conte et al.			
	BO	5,508,040	4/16/96	Chen			
	BP	5,549,913	8/27/96	Colombo et al.			
	BQ	5,609,590	3/11/97	Herbig et al.			
	BR	5,626,874	5/6/97	Conte et al.			
	BS	5,650,169	7/22/97	Conte et al.			
	BT	5,651,985	7/29/97	Penners et al.			
	BU	5,681,583	10/28/97	Conte et al.			
	BV	5,688,776	11/18/97	Bauer et al.			
	BW	5,736,159	4/7/98	Chen et al.			
	BX	5,780,057	7/14/98	Conte et al.			
	BY	5,811,126	9/22/98	Krishnamurthy			
	BZ	5,837,379	11/17/98	Chen et al.			
	CA	5,840,329	11/24/98	Bai			
	CB	5,861,173	1/19/99	Nishioka et al.			
	CC	5,897,874	4/27/99	Stevens et al.			
	CD	5,916,595	6/29/99	Chen et al.			
	CE	6,033,685	3/7/00	Qiu et al.			
	CF	6,207,197	3/27/01	Illum et al.			
	CG	6,261,601	7/17/01	Talwar et al.			
	CH	6,340,475	01/22/02	Shell et al.			
	CI	6,368,628	4/9/02	Seth			5/26/00
	CJ	6,451,808	9/17/02	Cowles			10/17/00
J	CK	6,488,962	12/3/02	Berner et al.			6/20/00

Examiner Signature		Date Considered	9/04
--------------------	---	-----------------	------

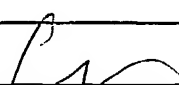
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			<i>Complete if Known</i>		
			Application Number	10/024,932	
			Filing Date	December 18, 2001	
			First Named Inventor	Bret BERNER et al.	
			Art Unit	1615	
			Examiner Name	Edward J. WEBMAN	
Sheet	2	of	3	Attorney Docket Number	3100-0001.20

CL	2001/0018070	8/30/01	Shell et al.			
CM	Serial No. 09/425,491		Shell et al.			10/22/99
CN	Serial No. 10/029,134		Gusler et al.			10/25/01
CO	Serial No. 10/045,823		Shell et al.			11/6/01
CP	Serial No. 10/066,146		Lim et al.			2/1/02
CQ	Serial No. 10/152,914		Fara et al.			5/20/02

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Foreign Patent Document No.	Publication Date	Country	Class	Subclass	T
	CR	EP 0598309 B1	1/28/98	Europe			
	CS	EP 0795324 A2	9/17/97	Europe			
	CT	WO 96/32097 A1	10/17/96	PCT			
	CU	WO 98/55107 A1	12/10/98	PCT			
	CV	WO 00/23045 A1	4/27/00	PCT			
	CW	WO 00/38650 A1	7/6/00	PCT			
	CX	WO 01/32217 A3	5/10/01	PCT			
	CY	WO 01/56544 A3	8/9/01	PCT			
	CZ	WO 01/97783 A1	12/27/01	PCT			
	DA	WO 02/083687 A1	10/24/02	PCT			

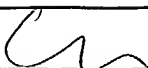
OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	DB	Abrahamsson, et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.	
	DC	Apicella et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.	
	DD	Columbo et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> 63:43-48.	
	DE	Davis et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.	
	DF	Deshpande et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention," <i>Pharmaceutical Research</i> 14(6):815-819.	
	DG	Gusler et al. (June 2001), "Pharmacokinetics of Metformin Gastric-Retentive Tablets in Healthy Volunteers," <i>The Journal of Clinical Pharmacology</i> 41(6):655-661.	
	DH	Huber et al. (1966), "Utilization of Hydrophilic Gums for the Control of Drug Release from Tablet Formulations. I. Disintegration and Dissolution Behavior," <i>Journal of Pharmaceutical Sciences</i> 55(9):974-976.	
	DI	Hwang et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 15(3):243-284.	
	DJ	Kim (1995), "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," <i>Journal of Pharmaceutical Sciences</i> 84(3):303-306.	
	DK	Korsmeyer et al. (1983), "Mechanisms of Solute Release from Porous Hydrophilic Polymers," <i>International Journal of Pharmaceutics</i> 15:25-35.	

Examiner Signature	Date Considered
	9/04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/024,932		
		Filing Date	December 18, 2001		
		First Named Inventor	Bret BERNER et al.		
		Art Unit	1615		
		Examiner Name	Edward J. WEBMAN		
Sheet	3	of	3	Attorney Docket Number	3100-0001.20

OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
J	DL	Maggi et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in Controlled Release Dosage Forms," <i>International Journal of Pharmaceutics</i> 195:229-238.	
J	DM	Rao et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> 48:1-13.	
J	DN	Reynolds et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> 87(9):1115-1123.	
J	DO	Siepmann et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> 16(11):1748-1756.	
J	DP	Yang et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.	

Examiner Signature		Date Considered	9/04
--------------------	---	-----------------	------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.